Theories on purported negotiations between TPPs and physicians

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS	Judge Patti B. Saris

MERITS REPORT AND DECLARATION OF GREGORY K. BELL, Ph.D., ON BEHALF OF TRACK 1 DEFENDANTS

March 22, 2006

V. PRIVATE PAYORS[180]

93. For many of the reasons discussed above, Dr. Hartman's expectations theory fails to provide a foundation for liability and damages related to Class 3, consumers and TPPs who paid for PADs based on contracts expressly using AWP outside of the Medicare Part B context. In addition, Dr. Hartman's theory founders on the competition that exists among TPPs and physician providers in the negotiation of reimbursement rates. If TPPs had been able to negotiate lower reimbursement rates, presumably they would have done so. In fact, although TPPs were aware of the generally lower reimbursement rates being paid through Medicare Part B, they were still only able to negotiate reimbursement schedules that tended to exceed Medicare Part B rates. This section of the report provides further discussion regarding the information available to TPPs, the role of competition in the setting of reimbursement rates for PADs, and the broader objectives of TPPs when negotiating reimbursement rates for PADs.

A. Information available

94. Plaintiffs' claims and Dr. Hartman's theory are predicated on the assumption that private payors were not aware of large differences between AWP and acquisition costs. Contrary to this assumption, however, TPPs—who can be sophisticated purchasing agents or may contract for such service through benefits consultants—had access to a wealth of information regarding pricing practices in the pharmaceutical industry throughout the class period. Some were purchasing PADs through other segments of their operations, such as a staff-model HMOs; others, such as CIGNA, were Medicare carriers; and all were or could have become familiar with the contracting practices of pharmaceutical manufacturers when faced with therapeutic or generic competition. A payor with concerns or curiosity regarding pharmaceutical acquisition costs and price concessions had numerous sources available to inform its reimbursement operations, including public studies of reimbursements and acquisition costs, price and reimbursement

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180 See Appendix C for a more extensive discussion of the information on pharmaceutical pricing that was available from non-government publications prior to and during the class period.

schedules released by the federal government, publicly broadcast addresses by the President of the United States, the business and popular press, policy discussions and debate regarding reimbursement methods for public programs (e.g., Medicare and Medicaid), and specialized market research and data sources regarding pharmaceutical prices. The abundance of information ensures that any payor exercising due diligence in the management of PAD reimbursements would be able to determine the availability and general magnitudes of price concessions by manufacturers.

95. I understand that one might question the extent to which the government studies were truly accessible to the TPPs at issue in this case. In fact, private payors tend to be aware of and track changes in reimbursement policies employed by public payors. This is not surprising as the public payors (Medicare, Medicaid, VA, and DOD) tend to be the largest single payors in the healthcare system. There are several prominent examples of how private sector payors have followed government programs in reforming reimbursement systems. For example, Medicare's prospective payment system ("PPS") for hospital care, implemented in 1983, bases reimbursements on diagnosis-related groups ("DRGs"). A wide variety of third-party payors adapted elements of this system for their own use over the next decade, including workers' compensation systems, more than one-half of the Blue Cross and Blue Shield Association member plans, many other commercial health plans, several self-insured employers, and a few employer coalitions.[181] Similarly, in 1993, after Medicare began implementing the Resource Based Relative Value System for procedures performed in a physician office, similar reimbursement systems were introduced as replacements for charges-based systems in one-third of the public and private payors surveyed.[182]

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181 Carter, Grace M. et al, "Use of Diagnosis-Related Groups by Non-Medicare Payers," *Health Care Financing Review*, Winter 1994, pp. 127–158 at 127.

182 McCormick, Lauren A. and Russel T. Burge, "Diffusion of Medicare's RBRVS and Related Physician Payment Policies," *Health Care Financing Review*, December 22, 1994, p. 159.

96. Many private payors also have adopted or adapted Medicare's HCPCS level II code infrastructure in designing their own reimbursement systems for PADs.[183] Some of these payors base PAD reimbursement directly on the Medicare system, including using the Medicare rates (or a percentage of these rates), HCPCS Level II codes, and RBRVS to process the claims.[184] Further, some private payors have expressed concern that their reimbursement rates would not be seen as competitive if they deviated from the traditional Medicare-based system. For example, Intermountain Health Care ("IHC") feels that market dynamics require it to maintain its reimbursements at levels which are 10 percent higher than those of Medicare Part B.[185] Finally, some private payors are evaluating a move to ASP-based reimbursement, following Medicare's lead under the MMA.[186]

97. Private payors also had access to the public press and its comments regarding pharmaceutical pricing and reimbursement. Throughout the class period, numerous national and regional outlets for public sector information discussed the role of AWP as a pricing benchmark and verified the existence of frequent discounting. For example, in a 1989 *Arkansas-Democrat Gazette* article, Bill McCutcheon, a regional administrator for HCFA, was quoted as saying, "Numerous studies and open admission by the people who publish those prices [AWPs] has shown that the average wholesale price doesn't represent the actual cost to pharmacies by any stretch of the imagination."[187] Similarly, a 1996 article

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183 See Deposition of Dan Dragalin, MultiPlan, September 17, 2004 ("Dragalin (MultiPlan) Deposition"), pp. 81-83; and Deposition of Mickey Brown, BCBS Mississippi, September 17, 2004 ("Brown (BCBS-Mississippi) Deposition"), p. 41.

184 Dragalin (MultiPlan) Deposition, pp. 47–48; Deposition of Eric Cannon, IHC Healthplans, September 13, 2004 ("Cannon (IHC) Deposition"), pp. 154–157.

185 Cannon (IHC) Deposition, p. 154.

186 In addition, by converting to an ASP-based system, private payors would minimize the disruption that might otherwise occur if medical publishers stop publishing AWP. First DataBank, for example, no longer publishes an AWP, instead relying on Average Benchmark Price ("ABP"). (See *The Prescription Drug Benefit Cost and Plan Design Survey Report*, The Pharmacy Benefit Management Institute, Inc., 2005, p. 8.) Eric Cannon testified that IHC Health Plans is now using R.J. Health as its source of reimbursement rates for PADs. (See Cannon (IHC) Deposition, pp. 135-136.)

187 "Pharmacists Face Big Losses under Proposal, Official Says," *Arkansas Democrat-Gazette*, March 23, 1989. Similarly, in the context of SADs, the *Lexington Herald-Leader* in 1987 quoted the comments of David Feinberg, a top Pennsylvania Medicaid official, that the Average Wholesale Price: "just doesn't mean anything. It has no connection to what pharmacists really purchase the

from *Barron's* noted that "[f]or many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60%-90% below the so-called average wholesaler price, or AWP, used in reimbursement claims."[188]

98. A diligent payor or other participant in the pharmaceutical industry also has additional sources of information available to evaluate manufacturer price concessions. Parties are able to purchase pricing data from established vendors. IMS Health ("IMS"), for example, is a recognized global supplier of pharmaceutical and healthcare data. During the class period, IMS provided a number of data products ("audits") that provided information regarding the existence of pharmaceutical price concessions.

99. Finally, in early 2002, the current litigation took shape.[189] The litigation announced that there were significant differences between AWP and acquisition costs and that different purchasers paid different prices. Accordingly, the fraud alleged by Plaintiffs, even if it existed (and I believe it did not), could not have persisted beyond these filings as Plaintiffs would have been aware of the existence of discounts from AWP.

100. Deposition testimony from payors and benefits consultants demonstrates an awareness of information that was publicly-available during the period of interest. Consider the following.

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drug for." (Miller, John Winn, "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars," *Lexington Herald-Leader*, July 5, 1987, p. A1.)

188 Alpert, Bill, "Hooked on Drugs," *Barron's*, June 10, 1996, pp. 15–18. For a more complete list of examples, see Appendix C.

189 I understand that Plaintiffs filed their first complaint in this matter on July 16, 2002. Prescription Access Litigation filed a similar complaint on December 20, 2001. (See "Consumer Groups Charge Industry-Wide Price Manipulation—Over $800 Million in Illegal Profits from Medicare & Medicare Patients; Federal Lawsuit Charges 28 Drug Companies with RICO, State and Federal Anti-Trust, and Consumer Protection Violations," *PR Newswire*, Boston, December 20, 2001.)

- Gary M. Owens of Independence Blue Cross ("IBC") testified about the wealth of information available and for which he is responsible within the scope of his position.[190]
- Christopher Brecht, the Chief Operations Officer of third party administrator Carday Associates, Inc. ("Carday"), testified on behalf of Man-U Service Contract Trust Fund ("Man-U") and identified sources for information on the healthcare industry reviewed by Carday and the information provided by benefits consultant The Segal Company ("Segal").[191]
- Edward Kaplan, the national health practice leader at Segal, a benefits consultancy, testified that in addition to a library of relevant material in each Segal office and a system by which relevant information was directed to health practice managers, Segal has reviewed studies by government agencies (including the GAO, CMS, and the Agency for Healthcare Policy Research ("AHCPR")) since at least 1993.[192]

101. As noted above, in the discussion of Classes 1 and 2, there is no foundation for Dr. Hartman's theory that payors expected a "reasonably predictable" relationship between AWP and acquisition costs. The 1992 OIG report that Dr. Hartman cites concludes that "there is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of the physician's acquisition

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190 "All of the knowledge that I acquire about pharmaceutical reimbursement, and for that matter managed care reimbursement, is within the scope of my job. Basically, that information can come in from any number of sources, including journals that may contain articles about how reimbursement is being performed, it can be through Internet updates or advisories, it can be through mailings or reading material that is forwarded to me either through the mail or from another colleague, it can be with my direct discussions with the management team and the pharmacy services department, it could be through personal encounters with other colleagues at IBC." (Owens (IBC) Deposition, p. 58.)

191 Carday's sources of information included "Various updates from consultants, the international foundation, Society for Professional Benefit Plan Administrators, and a periodical produced by Tolly International." (Deposition of Christopher Brecht, June 3, 2004, p. 19.)

192 Deposition of Edward Kaplan, National Health Practice Leader, Segal, July 12, 2004 ("Kaplan (Segal) Deposition"), pp. 71–72. AHCPR is now known as the Agency for Healthcare Research and Quality ("AHRQ").

cost ...."[193] Consistent with the OIG's conclusion, several payors have testified that they did not have consistent (or any) expectations about the relationship between physician acquisition costs and AWP when setting reimbursement rates. For example:

- IBC did not have any expectation as to the relationship between AWP and acquisition costs when setting the reimbursement rates for PADs;[194]
- Coventry Health Care's ("Coventry") reimbursement rates are unaffected by acquisition cost or consideration of physician profit margins;[195] and
- Anthem Blue Cross Blue Shield ("Anthem BCBS") does not include providers' acquisition costs for drugs in their determination of reimbursement rates.[196]

102. Nonetheless, Dr. Hartman claims to find further support for his 30 percent liability threshold among members of Class 3 by noting that there is approximately a 30 percent range in the "discounts" from AWP in reimbursement rates negotiated between payors and health care providers, as noted by contracts produced in this case and by a survey of contracts performed on behalf of MedPAC.[197] Rather than support his position, however, the comparison to contracted reimbursement rates demonstrates two inconsistencies in Dr. Hartman's approach.

103. First, Dr. Hartman fails to recognize that there is a difference between a range of expected price discounts (between manufacturers and providers) and the range of

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193 OIG November 1992, Appendix II.

194 Owens (IBC) Deposition, p. 162. In fact, before joining Delaware Valley HMO as its medical officer, Dr. Owens was a family practitioner. In his capacity as a sole practitioner, Dr. Owens expected to be reimbursed more than his acquisition cost for pharmaceuticals: "I wanted to be paid more for the drug than I paid for it, so that I would remain whole on administering the drug." (Owens (IBC) Deposition, p. 25.)

195 Deposition of J. Russell Hailey, Chief Pharmacy Officer and Vice President of Pharmaceutical Services, Coventry, August 4, 2004 ("Hailey (Coventry) Deposition"), pp. 151–152.

196 Spahn (Anthem BCBS) Deposition, p. 93.

197 MedPAC March 2003. This study relies upon a study performed by Dyckman & Associates for MedPAC, which was published in August 2003 as *Survey of Health Plans Concerning Physician Fees and Payment Methodology*.

expected contract rates (between payors and providers). Acquisition cost discounts and contracted reimbursement rates are separate concepts, relying on the interaction of different parties from the pharmaceutical industry and subject to different economic pressures. For example, consider an oncology facility with a world-class reputation. Such a facility might be expected to negotiate price discounts from manufacturers (perhaps through reputation effects or volume) and might also be expected to negotiate lucrative reimbursement terms from providers who value including this facility in a network of providers. In this situation, the acquisition cost and reimbursement rate discussions are correlated, but negatively! The acquisition cost is lower than average, the reimbursement rate is higher than average, and the outcome is determined by provider characteristics (i.e., reputation), not the payor's expectations about a relationship between AWP and acquisition cost.

104. Second, and even more compelling, Dr. Hartman's reference to a reimbursement range that extends up to AWP plus 15 percent[198] proves that factors other than expected acquisition cost affect negotiated reimbursement rates. Even if payors expected providers to have received no price concessions, contracts that reimburse providers in excess of AWP demonstrate that payors either choose to include other factors in their reimbursement decisions or that payors lack the negotiating power to require lower reimbursement rates.

I. Industry structure and information

105. A number of payors are vertically integrated, that is, they have acquired or developed the capabilities of other services in the pharmaceutical reimbursement or distribution chain. There are five types of vertical integration of interest: mail order, specialty pharmacy or distribution, captive PBM, staff model HMO, and hospital ownership. When a payor undertakes such a business venture, it also informs itself of providers' drug acquisition costs and price concessions.

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198 Hartman Liability Report, ¶ 22 (c), which refers to Table 9-2 of the MedPAC June 2003.

106. Exhibit E provides a summary of those payors with vertical relationships of interest, identified either through publicly-available documents or through deposition testimony. Whether through operation of mail-order pharmacies, specialty pharmacies, captive PBMs, staff-model HMOs, or hospitals, these payors had direct evidence of acquisition costs and could have used such information in negotiation or plan benefit design. Nationally, these payors represent nearly 100 million insured lives, nearly 2 million in Massachusetts.

107. First, many payors—such as Aetna Inc. ("Aetna"), CIGNA, and WellPoint Inc. ("WellPoint")—provide their own mail-order pharmacy services.[199] By operating mail-order pharmacies, these payors have direct exposure to the pricing policies of manufacturers. The payors use their mail order capabilities and formulary controls to extract price concessions from manufacturers seeking to compete for an increased share of the prescriptions in a therapeutic category that will be dispensed through mail order. In addition, information gleaned through mail-order operations informs other operations. For example, acquisition costs from mail-order operations may be used in the calculation of TPP's MAC prices, providing a payor with mail-order operations additional insight into the acquisition costs of multi-source products and the potential cost savings from MAC operations.

108. Mail order operations are primarily oriented around SADs, but with respect to PADs, to the extent that these payors were not already aware of the price competition among manufacturers with competing pharmaceuticals, the experience with their mail order operations would make them aware. Further, some payors actually use courier services to deliver certain oncology medications to patients, who then carry the medications to the physician's office for

[199] In September 2003, Atlantic Information Services, Inc. ("AIS") reported the following mail-order script volumes for Quarter 2, 2003: Aetna Pharmacy Management, 4.6 million; CIGNA Pharmacy Management, 5.0 million; and WellPoint Pharmacy Management, 3.3 million. ("Mail-order Rates, Capabilities Foster Increased Competitiveness among PBMs," Drug Cost Management Report, September 12, 2003.)

administration.[200] Industry observers also have noted that the prevalence of PAD distribution through mail has been increasing since the site of care has shifted from the hospitals to physician offices and even home care.[201]

109. Second, some major payors—such as Aetna, Anthem BCBS, CIGNA, HealthNet Inc. ("HealthNet"), Humana Healthplan Inc. ("Humana"), Kaiser Permanente ("Kaiser"),[202] PacifiCare Health Systems Inc. ("PacifiCare"), United HealthCare Services Inc. ("UHC"), WellPoint, and a collection of Midwest Blue Cross plans—have gone beyond mail-order pharmacy and developed their own full PBM services.[203] In addition to direct purchasing for mail-order operations, payors with captive PBMs also extract price concessions from manufacturers by virtue of their control over the formulary.[204] Again, even if these payors only managed pharmacy benefits for SADs, the experience with their PBM operations would make them aware of potential price concessions with respect to PADs to the extent that these payors were not already aware of the price competition among manufacturers with competing pharmaceuticals.

110. Third, some payors have developed specialty distributor and specialty pharmacy operations for the management of PADs, including Aetna (Aetna Specialty Pharmacy, LLC), Anthem BCBS (Anthem Prescription Management, LLC) CIGNA (CIGNA Tel-Drug), Highmark BCBS ("Highmark") (Medmark

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200 March, Astara, "Brown Bagging Chemotherapy Drugs," *Oncology Issues*, July/August 2001, pp. 23–28 at 24.

201 "Chains Still Lead, But Food Stores, Mail-Order Deliver Hefty Gains," *Drug Store News*, May 21, 2001, accessed at http://www.findarticles.com/p/articles/mi_m3374/is_7_23/ai_75030573/print. This article quotes Doug Long, Vice President of Industry Relations at IMS Health: "Mail order drug sales through the institutional markets, such as oncology, dialysis and radiology clinics, are being driven by the switch from in-patient to out-patient care."

202 Kaiser includes Kaiser Foundation Health Plans, Kaiser Foundation Hospitals, and Permanente Medical Groups. See http://employers.kaiserpermanente.org/kpweb/structurekp/entrypage.do, accessed March 21, 2006.

203 See Exhibit E and the sources listed therein.

204 Many of these formularies explicitly include certain PADs, such as the anti-anemia and anti-emetic products, and some include anti-neoplastics. For example, BMS's VePesid is on the non-preferred tier of Cigna's three-tier formulary. (Accessed at https://secure.cigna.com/cgi-bin/health/sdrug_list.cgi.)

Inc./Fisher SPS), and WellPoint (PrecisionRx Specialty Solutions).[205] Through the operation of these capabilities, payors would be purchasing directly from manufacturers and negotiating with manufacturers to extract price concessions as the manufacturers compete for a greater share of the specialty pharmacy dispensing and reimbursement. In addition, the payor could also gather information on costs accruing to physicians dispensing PADs routed through the related specialty distributors.

111. Vendors of pharmacy benefit management services for PADs, known as specialty pharmacy programs ("SPPs"), became more prevalent over the course of the class period. In 1978, Caremark's predecessor Baxter Healthcare began to deliver hemophilia homecare.[206] In the early 1980s, Accredo's predecessor began to distribute clotting factor and Protropin, a human growth hormone.[207] A 2004 *Drug Cost Management Report* article confirms that payor interests in specialty pharmacy had increased in the last several years and reports that, "Of MCOs [Managed Care Organizations] responding, 80% said they had conducted a competitive procurement process for specialty pharmaceuticals during the past two years. These MCOs solicited bids from three to 11 specialty pharmacy vendors, with an average of five vendors included in the procurement process."[208] For example, Mike Beaderstadt of John Deere Health Care, Inc. ("John Deere") recalls that his company insisted that Remicade, Lupron, and Synagis be sourced from a specialty pharmacy because the specialty pharmacy would demand

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205 "Specialty Pharmacy Market Offers Expansion Opportunity for PBMs," *Drug Cost Management Report*, September 12, 2003. See also Exhibit E.

206 Caremark, "Caremark History," available at http://www.caremark.com/wps/portal/_s.155/3359?cms=CMS-2-003599 accessed September 8, 2005, ("Caremark 2005").

207 Accredo, "About Accredo: History," available at http://www.accredohealth.net/ahi/about/history.htm , accessed September 8, 2005, ("Accredo 2005").

208 AIS, "Survey Spots MCOs' Contracting Goals for Specialty Pharmacy," *Drug Cost Management Report*, July 30, 2004 ("AIS 2004"), pp. 1-2.

significantly lower reimbursement than would the physicians who purchased the drugs themselves.[209]

112. Fourth, in staff-model health maintenance organizations ("staff-model HMOs"), pharmacists and physicians are employees of the insurer, the pharmacies and medical facilities are owned by the insurer, and a captive PBM generally manages pharmacy benefits. As such these organizations purchase pharmaceuticals and negotiate with manufacturers competing for a larger share of the organization's prescription business. These organizations thus have full knowledge of the pricing practices of the manufacturers, at least as they apply to their organizations. Staff-model HMOs are also often part of larger TPPs that reimburse the PADs at issue through other types of managed care organizations.[210] Further, these organizations compete with other payors to provide healthcare benefits to employers and other organizations. As such, the effect of their knowledge of pharmaceutical pricing is reflected in the prices at which they are willing to offer their healthcare benefits package.

113. Finally, some payors have acquired part or full ownership of hospitals. IHC Health Plans' corporate parent owns 21 hospitals and a number of physician groups, and IHC Corporate Pharmacy Services purchases pharmaceuticals on their behalf.[211] Like staff-model HMOs, hospitals use their control over the pharmaceuticals dispensed in their facilities to negotiate price concessions from pharmaceutical manufacturers. Through ownership of hospitals and medical facilities, health insurers have direct information on the negotiation practices used by and price concessions available from pharmaceutical manufacturers.

114. Payors and other industry participants thus operated in an environment replete with information regarding the difference between acquisition cost and AWP, including government studies, public reports, the experiences of their personnel, and their experience in administering public programs or negotiating private

209 Beaderstadt (John Deere) Deposition, pp. 77–78.

210 Exhibit E identifies 13 TPPs with staff model HMO operations.

211 Cannon (IHC) Deposition, p. 24.

contracts with providers. Payors have demonstrated through deposition testimony and reimbursement policies that they were aware that the difference between acquisition cost and AWP varied greatly by drug, depending on competitive circumstances and drug type.[212] Similarly, information that was available to payors during the period of interest showed substantial variation in discounts for single-source PADs, with rates that exceeded the 30 percent liability threshold posited by Dr. Hartman (and were even higher and more variable for multi-source PADs). While it is unlikely that any payor had full information on all price concessions across all products or that any manufacturer made all payors aware of all price concessions for its products, nonetheless, as will be discussed below, full information was not necessary to secure efficient or competitive contracts for the reimbursement of PADs.

B. Competition and negotiation among TPPs and physicians

115. Dr. Hartman asserts that payors would have necessarily negotiated lower drug reimbursement rates had they been aware of the difference between physician acquisition costs and AWP. I do not agree.

116. Payors and physician providers meet in the marketplace and negotiate over the fee schedule. The two parties have conflicting objectives. Payors compete with each other for access to physician providers but are interested in paying as little as possible, subject to the need to maintain the quality of their provider networks.[213] For example, Dr. Owens said he believed that competition among payors gave physicians leverage in their negotiations with payors, because physicians knew

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212 CIGNA, for example, altered the reimbursement terms for 13 PADs after it recognized that generic availability had reduced the acquisition prices. "Our change that we made was in reaction to the result of competitive market forces. Generic drugs were introduced that drove down the acquisition cost, the cost of the product in the marketplace." (Herbold (CIGNA) Deposition, p. 86.) Other payors, such as Anthem Prescription Management, recognized that therapeutic competition reduced SAD acquisition prices. (Deposition of Robert Bell, Director of Trade Relations, Anthem PM, December 1, 2004 ("Bell (Anthem PM) Deposition"), pp. 54–57.)

213 Note that this applies to public as well as private payors. For example, Medicare reimbursement reforms and proposals frequently generate discussion of whether healthcare providers would participate if reimbursements were lowered. See, for example, the discussion following passage of the MMA when some oncologists warned that "they may refuse altogether to treat Medicare patients ...." (Harris, Gardner "Among Cancer Doctors, A Medicare Revolt," *The New York Times*, March 11, 2004, pp. C1, C4).

that payors needed them in their networks.[214] Physician providers compete with each other for access to the payors' members but are interested in being paid as much as possible, subject to the number of members to whom they have access. Dr. Hartman does not articulate how improved knowledge regarding acquisition costs would influence the outcome of these negotiations. Furthermore, even under Dr. Hartman's expectations theory, payors participating in the negotiations would have no knowledge of the actual acquisition costs being paid by different providers and neither the payors nor the providers would necessarily know how those acquisition costs would evolve over the duration of the contract. Finally, the pharmaceutical reimbursement rate is only one element of the contracts negotiated between payors and providers.

117. As even Dr. Hartman notes, pharmaceutical price concessions depend upon the individual characteristics of buyers and sellers, and the negotiating position and abilities of the parties involved.[215] Accordingly, it must be the case that pharmaceutical purchasers do not negotiate with manufacturers by simply applying a standard, preordained discount to a reimbursement benchmark. Different purchasers may negotiate different prices for the pharmaceuticals at issue. Similar dynamics and conclusions apply to providers who negotiate with payors over reimbursement levels.

118. As a result, it is to be expected that the reimbursement rates ultimately negotiated may yield different profits per product and service at the time of signing the contract and over the course of the contract. The profits available to physicians will differ for products and services, and different physicians will realize different profits as a result of their reimbursement contracts and purchasing options and agreements.

119. Evidence produced in this case demonstrates that payors were aware of the variation in the difference between AWP and drug acquisition cost on a drug-by-

214 Owens (IBC) Deposition, pp. 49-50.

215 Hartman Class Rebuttal, 2004, ¶ 54.

drug basis. Mike Beaderstadt, at John Deere, noted that AWP did not have any consistent relationship with actual acquisition cost.[216] Joe Spahn, Senior Health Care Consultant, agreed that Anthem BCBS had "no particular expectations" of providers' costs.[217] Despite their awareness of variations in acquisition cost, payors often negotiate a single reimbursement rate, expressed as a percentage of the benchmark AWP, for all PADs.[218] As a result, payors expect that there will be some drugs for which reimbursement is closer to or farther from the providers' acquisition cost.

120. Payors expect to be unaffected by the availability of greater information on acquisition costs. For example, David Morris, Manager, Pharmacy Management Department at Anthem BCBS, noted that reimbursement rates are determined by negotiation and what the market will bear, not acquisition cost.[219] Mr. Morris's representations were recently confirmed, as Virginia Oncology Associates P.C., the largest network of cancer specialists in Virginia, walked out of negotiations with Anthem BCBS in December 2005 after noting that Anthem's offer of reimbursement rates for more than 30 cancer drugs was not fair or adequate.[220] Similarly, James Messinger, Vice President of Managed Pharmacy Products at Union Labor Life Insurance Company ("ULLICO"), noted that more information on pharmacies' acquisition price would not affect reimbursement formulae or reimbursement payments.[221]

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216 Beaderstadt (John Deere) Deposition, pp. 72–73.

217 Spahn (Anthem BCBS) Deposition, pp. 97-98.

218 "From a global perspective, average wholesale price minus a set percent is what we look at from a global perspective. We don't get down to specific – specific by product, by product." (Deposition of Timothy Hopkins, Executive Director of Retail and Mail Order Operations, Anthem Prescription Management, November 30, 2004 ("Hopkins (Anthem PM) Deposition"), p. 77) See also Owens (IBC) Deposition, pp. 37–38: "Q. Is it your understanding that someone else at Independence Blue Cross engages in a line item by line item negotiation with doctors over the reimbursement under a fee schedule? A. No one ever does that."

219 Deposition of David B. Morris, Head of the Pharmacy Management Department, Anthem BCBS, January 5, 2005 ("Morris (Anthem BCBS) Deposition"), p. 69.

220 Connolly, Allison, "Va. Oncology Associates and Anthem Extend Talks," *The Virginian-Pilot*, January 4, 2006. The parties agreed to extend their previous contract until April 30, 2006.

221 Deposition of James P. Messinger, Vice President of Managed Pharmacy Products at ULLICO, October 22, 2004 ("Messinger (ULLICO) Deposition"), pp. 64–65.

121. As noted above, when negotiating with physician providers, payors focus on paying as little as possible, subject to maintaining a network adequate to the payor's needs, rather than calculating a specific physician's acquisition costs. Examples from the deposition testimony are as follows.

- Mr. Spahn of Anthem BCBS agreed that Anthem's biggest concern in negotiating with physicians was maintaining an adequate provider network.[222]
- Dr. Owens agreed that IBC intended to offer "sufficient reimbursement to enable them to retain their robust network" and that IBC had done so since 1991.[223] Dr. Owens also noted that IBC has had to increase reimbursement to physicians because of "market forces."[224]

122. In summary, payors negotiate reimbursement rates and other financial terms with providers to achieve established operating goals, including ensuring sufficient provider participation in healthcare networks, appropriately encouraging patient care to be delivered in the most efficient setting, and promoting the use of generic drugs. Payors and physician providers consider the full scope of the financial terms under negotiation when attempting to meet their objectives, and will trade gains in some financial areas for losses in others, so that the net terms of the negotiation are acceptable. As noted by Ms. Herbold of CIGNA, "The negotiation is completed in whole, so negotiating all the physicians' services." She agreed that a physician definitely could "accept a lesser reimbursement for pharmaceutical products and instead demand a greater reimbursement for a particular service."[225] As a result, even if it were the case that some payors considered or had expectations about the difference between AWP and acquisition

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222 "Q. In order to maintain that provider network, does Anthem need to offer reimbursement rates that are sensitive to the market's demands? A. Yes. Q. So when we're referring to market dynamics and competitive dynamics, what we're really talking about is Anthem's need to maintain an adequate provider network, correct? A. Correct." (Spahn (Anthem BCBS) Deposition, pp. 54–55.)

223 Owens (IBC) Deposition, pp. 104-105.

224 Owens (IBC) Deposition, pp. 193, 201–202.

225 Herbold (CIGNA) Deposition, pp. 28–29.

cost, they would also recognize that pharmaceutical discounts were just one component of a larger financial relationship with providers.

123. Agreements in which payors reimbursed at or in excess of AWP indicate that there are more financial interactions between payors and providers than are considered in Dr. Hartman's expectations model. Evidence from payors and other sources provide at least three reasons for this behavior, all of which are inconsistent with Dr. Hartman's expectations model. Reimbursement rates in excess of acquisition costs might indicate:

- That payors received significantly more favorable terms in other aspects of the agreement with providers (e.g., a lower fee schedule for physician services);
- That payors are reimbursing more than pharmaceutical costs through the reimbursement rate, the "cross-subsidization" issue discussed earlier in this report;
- That payors are at a competitive disadvantage in securing provider participation, perhaps as a result of advantages due to provider reputation or relative scarcity.[226]

124. Dr. Hartman's expectations model is inconsistent with each potential explanation of reimbursement rates in excess of acquisition costs. If such contracts indicate that the payor is including other factors in the reimbursement decision, then Dr. Hartman's expectation needs to include payors' expectations for those other factors to understand how much of the payor behavior is motivated by the alleged actions by pharmaceutical manufacturers. If such contracts instead indicate that the payor is at a competitive disadvantage and must pay higher rates to secure provider participation, then a payor's expectations of pharmaceutical discounts are irrelevant.

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[226] See, for example, Owens (IBC) Deposition, pp. 49–50.

i. **Disadvantages of transparency**

125. Contrary to the premise of Dr. Hartman's expectations theory, knowing acquisition costs could only affect the outcome of payor-provider negotiations if the payor were previously operating inefficiently in maximizing profits or services. If payors are operating efficiently, they are either already forcing reimbursement rates down through the competitive process of negotiating provider contracts or there are other competitive factors that limit reimbursement reduction opportunities.[227] It is not evident that new information or expectations would provide the payors with additional negotiating leverage such that the costs of providing healthcare services would decline.

126. Not only would the arrival of additional information not provide a better negotiating position for payors, but it might actually harm those payors who have operated efficiently. For example, payors understand that increased price transparency could erode the competitive advantages they enjoy relative to other payors. Coventry, for example, considers its reimbursement rates to be trade secrets and feels that it would be competitively disadvantaged if forced to disclose its rates.[228] IBC, too, considers its rates to be confidential.[229] Similarly, with respect to generic SADs, Michael Baca, Executive Director of Financial Operations at HealthNet Pharmaceutical Services, described HealthNet's MAC methodology as "a highly confidential, proprietary piece of information that could really hurt our competitive situation if we were to disclose that."[230]

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227 This result is not sensitive to the profit status of the payor. There exists ample academic evidence that for-profit, non-profit, and not-for-profit entities are virtually indistinguishable in their efforts to maximize returns. Instead, the type of facility affects how those returns are dispensed. For example, see: Edward C. Norton and Douglas Staiger, "How Hospital Ownership Affects Access to Care for the Uninsured," *Rand Journal of Economics*, 1994, pp. 171–185; or Frank Sloan, Gabriel Picone, D Taylor, and Shin-Yi Chou, "Not-For-Profit Ownership and Cost and Quality of Care: Is There a Dime's Worth of Difference," in *Handbook of Health Economics*, Vol. 1, AJ Culyer and Joseph P. Newhouse (eds.), Elsevier, 2000, pp. 1141–1174.

228 Hailey (Coventry) Deposition, pp. 153-154. Mr. Hailey also testified that it is not Coventry's position that pharmaceutical manufacturers should disclose rebate and discount information. (Hailey (Coventry) Deposition, pp. 154–155.)

229 Owens (IBC) Deposition, p. 97.

230 Deposition of Michael Baca, Executive Director of Financial Operations, HealthNet, October 8, 2004, pp. 79–80.

ii. Conclusions

127. Thus, in addition to its failure to account for the abundance of information available regarding acquisition costs and AWP, Dr. Hartman's expectations approach is inconsistent with the competition among private payors and physician providers as they negotiate reimbursement rates. Most notably, payors do not condition their reimbursement policies on expectations of providers' acquisition costs or the relation of those costs to the AWP. Further, many payors were ambivalent about whether such information would be useful, as such information did not affect the outcome of their reimbursement negotiations.

128. To the extent that payors develop expectations regarding the difference between AWP and average acquisition price, they would understand that the difference would differ by drug, incorporating considerations of therapeutic and generic competition. Nonetheless, payors generally negotiate reimbursement for the entire bundle of drugs and physician services, not each line item individually. As a result, payors expect that there will be great variation in how close their reimbursement rate approximates acquisition cost for each drug. Payors know and expect this to be the case.[231]

C. Payors condone a profit on PADs

129. Health insurers compete for business—the provision of healthcare benefits to employers, health and labor funds, and even individuals. Health insurers compete based on benefit plan design, cost, and the breadth and quality of their network of healthcare providers. As a result, the commercial success of an insurer depends critically upon its ability to negotiate reimbursement contracts with health care providers at the lowest possible total cost while still offering a network of providers valued by the insurer's members.

130. There is also competition among providers for access to the members of the health insurer's plans. Where health insurers identify a network of preferred

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[231] For instance, payors may not revise their reimbursement rates for a product when generic versions of the product become available.

providers, those providers wanting to participate in the network compete by lowering the price at which they are willing to offer their services. Reimbursement for PADs is one element of that price.

131. Competition among health insurers for members and among providers for access to patients leads to reimbursement contracts that are negotiated between parties with opposing interests in a marketplace where each party generally faces competition. This competition precludes excess profits beyond those that are attributed to a party's market position. Competition among health insurers implies that any excess profits that they could generate would be re-invested in lower premiums and/or more generous benefit designs. If a lack of competition results in some providers negotiating relatively lucrative reimbursement contracts, then any negotiated reimbursement for PADs, whether benchmarked to AWP or not, would generate the same result over time.

132. Payors and society benefit from provider incentives to seek out the lowest costs of providing quality healthcare services, even if providers pocket the savings. Accordingly, it is appropriate that there be profit opportunities for physicians with respect to PADs—this provides an incentive to seek out the lowest possible acquisition costs for the products they dispense. The payors benefit because the profits that providers anticipate lead to competition among providers to offer payors and their members greater services at lower total cost.

133. To manage effectively the costs of their health plans, payors must generally consider how changes to one aspect of a plan might affect the other aspects of the plan. Consistent with these principles, payors may consciously encourage one type of service in order to avoid incurring the larger costs associated with alternative types of services. For example, a patient who fails to maintain a routine drug therapy regimen for the control of high blood pressure may ultimately be hospitalized for a heart attack or stroke, dramatically increasing the total cost of patient care to the payor (and to the patient who co-pays part of the cost of care). To this end, it was in the interest of both public and private payors

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris
	FILED UNDER SEAL

EXPERT REPORT OF JANUSZ A. ORDOVER

the differences between acquisition costs and AWPs and to more effectively negotiate reimbursement terms with physicians or physician groups.[23]

29. Of course I am not arguing, or even suggesting, that information on transaction spreads is perfect, ubiquitous, or disseminated immediately. However, the available evidence makes clear that there are many sources of qualitative and quantitative information regarding these spreads, which leads me to reasonably conclude that Medicare and TPPs alike were not (and should not have been) operating under the mistaken premise that AWP invariably represents a reliable predictor of acquisition costs.[24] Thus, as I explain in greater detail in the next section, in their negotiations with physicians, Medicare and TPPs would have – or should have – used whatever knowledge they had to control the margins between the reimbursed amounts and physicians' acquisition costs, taking into account the constraint that physicians require a certain margin on PADs (and other services) in order to earn an acceptable rate of return on their practices.

C. Pharmaceutical Industry Economics

30. Dr. Hartman's analysis of permissible spreads (or spreads that would arise in his but-for world) is also marred by his implausibly constricted view of what constitutes a permissible differential or spread between AWP (which I assume *arguendo* is the reimbursed amount) and acquisition costs. He takes the position that any differential above his promulgated threshold evidences fraudulent behavior and a lack of information by the payors and thus concludes that any differential in excess of 30% must stem from unlawful conduct aimed at defrauding payors. Similarly, Dr. Rosenthal interprets Dr. Hartman's "yardstick" as indicating that any amount of spread above 30%

[23] *See Id.* and the Appendix for examples of TPPs that employ individuals with experience in the provider community.

[24] In this context it is important to point out that from the perspective of the payor it is not important whether AWP is equal to AC but, rather whether there is a reasonably predictable relationship between AWP and the acquisition cost for a given drug or category of drugs.

is attributable to the "alleged fraud" while any amount up to 30% is the product of "[physician] market power, [and] other factors."[25] This is incorrect economics. It is obvious that the non-fraudulent spread can vary over time for any number of legitimate reasons that have nothing to do with the purported scheme to mislead or defraud Medicare and TPPs.

31. The opinions of Drs. Hartman and Rosenthal lead to an untenable conclusion that legitimate competition among drug manufacturers would be deemed fraudulent if it led to lower acquisition costs for PADs while resulting in a differential between acquisition costs and AWP exceeding 30%.[26] For example, if a pharmaceutical company, to better reflect competitive realities, offered discounts to physicians sufficient to create a differential between acquisition costs and AWP of 35% while holding the AWP unchanged, this conduct would be deemed unlawful by Drs. Hartman and Rosenthal.[27] In fact, their characterization of competitive spreads would condemn a drug company whose pricing behavior created a spread exceeding the 30% benchmark, even in the case where the spread resulted from a competition-driven reduction in acquisition costs that was intended to induce TPPs to promote the usage of the drug in physicians' offices. A finding of liability in this situation makes no economic sense: on the contrary, such pricing behavior creates desirable incentives to promote the drug to patients and to reduce healthcare system costs. Drs. Hartman and Rosenthal appear to reject a reasonable economic proposition that a higher available margin resulting from a reduction in acquisition costs will

[25] *See* Rosenthal Deposition at pp. 321-322.

[26] This point is also developed in Professor Scott-Morton's Report (*see* pp. 16, 28-29, and 32) and in Professor McFadden's Report (*see* Declaration of Daniel L. McFadden ("McFadden Report"), pp. 3-4).

[27] Indeed, Dr. Hartman's view seems to be that pharmaceutical manufacturers can legitimately compete on spread so long as that competition does not become so aggressive that the spread exceeds 30%. Dr. Hartman states that, "They're still competing on spread, but they're doing it within the bounds that are subject to my – to my legal threshold." (*See* Hartman Deposition at p. 1231.) I am aware of no economic principle that would condemn firms' behavior according to the test offered by Dr. Hartman.

eventually be eroded by payors in the negotiations over reimbursement rates.[28]

32. To better understand the economic factors underlying drug manufacturers' observed pricing behavior, it is useful to start with the simple example of a cereal manufacturer who wants to increase its market share. To meet this objective, the manufacturer may provide incentive payments to supermarkets while holding the wholesale price constant. The expectation is that competition among supermarkets will lead to a reduction in the retail price of the cereal, stimulate sales, and benefit consumers. Two aspects of this example are worth noting. First, the manufacturers' incentive payments initially cause a change in the spread between the retail price and the wholesale price. And second, consumers end up paying lower prices irrespective of whether they have any information about the supermarkets' net acquisition costs. Competition among grocery retailers operates to maintain a reasonable spread between prices at retail and supermarkets' net acquisition costs.

33. In the case of prescription drugs, the situation is more complex because consumers only pay a fraction (possibly zero) of the total charge for a drug while other payors cover the difference.[29] Hence, competitive forces operate in a more indirect fashion. In particular, to ensure that margins do not get out of line relative to the amounts doctors seek to earn from their practices, the marketplace relies upon competition among doctors for access to plan members and competition among payors to build and maintain attractive networks of providers while controlling the costs of operating the plans. Just as in the cereal example above, effective competition in the

[28] Persistence of a higher margin following an increase in the spread may reflect higher costs associated with the administration of the drug to the patients or other changes in the economics of medical practices.

[29] Patients can pay either a fixed amount per prescription or a fixed percentage of the cost of the prescription. In either case, they do not immediately bear the full costs of a price increase or obtain a full benefit from a price decrease.

prescription drug marketplace does not mean that the "wholesale" margins remain static or always at or below some maximum arbitrary permissible threshold. More to the point raised by the instant litigation is the fact that in the context of physician-administered drugs, manufacturers do not have access to the same share-shifting strategies as their cereal counterparts. A cereal manufacturer, in addition to offering incentive payments to grocery retailers, can lower wholesale prices and depend upon competition among retailers to pass along to consumers the benefits of lower wholesale prices which, in turn, would shift share toward the less expensive cereal.

34. For physician-administered drugs, however, such a strategy will not necessarily be effective in inducing additional sales. Because physician reimbursement is often based upon some level of discount off of AWP, a reduction in AWP likely would not benefit doctors relative to the spreads received on competing drugs. Thus, a reduction in AWP could potentially lead some doctors to shift away from the manufacturer's drug, all else being equal, as opposed to increase their usage of the drug.

35. Another potentially perverse consequence of the economic reasoning advanced by Plaintiffs and Dr. Hartman is that if information regarding manufacturers' discounting practices were instantaneously transmitted to payors this likely would lessen incentives to reduce acquisition costs to physicians and thus would tend to deprive consumers of the benefits of lower drug acquisition costs to the administering doctors. In fact, if disclosure of an increased spread (*i.e.*, higher discount) to Medicare or TPP is very quick, and the payors use that information to lower reimbursement rates to the doctors and/or force rival suppliers to make similar concessions very quickly, a manufacturer who lowers the ASP would achieve no lead time over its rivals and would thus garner little if any competitive advantage by offering the discounts in the first place. Indeed, payors' insistence on lower reimbursement rates would lessen the physicians' incentive to shift share and thus undermine the whole strategy. Simply stated, the discounting strategy would cease to provide an effective means of shifting

share, and hence manufacturers likely would scale back substantially the pricing incentives offered to physicians.[30] Insofar as such incentives ultimately lead to lower reimbursement rates, the attendant benefits to TPPs and consumers would be lost.

36. Building on their flawed assumption that drug manufacturers' pricing strategies are substantially opaque, Plaintiffs and Dr. Hartman contend that the putative fraudulent scheme caused payors to "substantially overpay" for certain drugs,[31] *i.e.*, to negotiate reimbursement rates that exceeded those that would have obtained in the assumed but-for world of pricing transparency. Conspicuously absent from Dr. Hartman's analysis is any economic assessment of how competition among payors to attract physicians to their networks and competition among physicians to attract patients to their practices would affect reimbursement rates negotiated between the two parties. Indeed, the methodology adopted by Dr. Hartman to derive the caps on non-fraudulent levels of the spread actively prevents him from factoring these market realities into his analysis. Moreover, in my understanding, his methodology leads him to assume that any amount of imperfect information[32] in the marketplace will lead to distorted outcomes, even if the competitive forces bearing on payors and physicians are operating well. Contrary to Dr. Hartman, it is my view that irrespective of the spread initially established by the manufacturer, even if the participants in the marketplace do not possess perfect information regarding the spreads, forces of competition will ultimately work to adjust reimbursement rates or

[30] Dr. Rosenthal acknowledged at her deposition that "there can be cases in which keeping discounts secret has economic benefits." (*See* Rosenthal Deposition at pp. 389-391.)

[31] *See, e.g.*, Amended Master Consolidated Class Action Complaint Modified Per The Court's Instruction At The November 21, 2003 Hearing With Amgen Amendments, at p. 34.

[32] While the evidence convincingly demonstrates that payors were aware of the differentials between AWP and provider acquisition costs, it is not my position that the dissemination of pricing information is in any way instantaneous. However, the existence of lags in the flow of information does not negate my overall conclusion that the competitive forces facing physicians and payors will eventually push reimbursement rates, and hence, consumers' expenditures as well, to levels consistent with the earnings required by doctors to sustain their practices.

overall returns on the practice, thereby bringing the costs of the health plans to the insureds to the level consistent with competition among drug companies, health plans, and physicians: that is to competitive levels.

37. The analytical flaw in Dr. Hartman's report which I discussed in the preceding paragraphs is also highlighted by Dr. Berndt in his report to Judge Saris. Dr. Berndt identifies a number of legitimate economic factors that influence the pricing behavior of drug manufacturers – and thus the spreads – including the drug's therapeutic class, the number of single-source, brand-name competing drugs in the same therapeutic class, whether any brands in the same therapeutic class are multi-source, and the time before the expected patent expiration and initial generic entry.[33] Consistent with my critique of Dr. Hartman, Dr. Berndt aptly summarizes the challenge facing Dr. Hartman's simplistic model of permissible spreads:

> "How can it be determined that at any given point in time, it is one or more of the above factors that affected and were largely responsible for the price decisions made by defendant manufacturers during the product's life cycle, rather than Defendants' alleged AWP scheme to collect inflated prescription drug payments? Simply examining and recording larger differences in percent 'spreads' between each AWPID drug and 'drugs not subject to this Litigation' will not be sufficient to establish reliably that any differential 'spread' is attributable solely, partly or not at all to the alleged AWP scheme to collect inflated prescription drug payments."[34]

IV. PLAINTIFFS' LIABILITY THEORY IS NOT APPLICABLE TO REMICADE

A. Introduction

38. In this section I examine the application and relevance of the Plaintiffs' theory of harm to Remicade (infliximab). I understand that Remicade is an

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[33] *See* Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, February 9, 2005, at p. 115.

[34] *Id.* p. 116.